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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,832	12/07/2001	Ewen F. Kirkness	PF105P1D2	8309

22195 7590 09/29/2003

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EXAMINER	
KEMMERER, ELIZABETH	

ART UNIT	PAPER NUMBER
1646	6

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/004,832	KIRKNESS ET AL.	
	Examiner	Art Unit	
	Elizabeth C. Kemmerer, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,15,17-19,22-25 and 27-59* is/are pending in the application.

4a) Of the above claim(s) *1,15,17-19 and 22-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,15,17-19,22-25 and 27-59* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2, 5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

Applicant's election with traverse of Group VI, claims 20-21, in Paper No. 4 (11 April 2003) is acknowledged. The traversal is on the ground(s) that the restriction requirement did not establish a search burden, and that all of the groups could have been examined together without a search burden. This is not found persuasive because there would be a search burden to examine all of the groups in one application. Contrary to Applicant's assertion, the search required for the elected invention (method of administering HMF protein) would not reveal information relative to antibodies, nucleic acids encoding the HMF, methods of screening for agonists, diagnosis methods, etc. For example, the protein used in a therapeutic method reference could easily be isolated from its natural source without the skilled artisan having to resort to the nucleic acids or antibodies. Therefore, inclusion of all of the groups in one patent application would present the examiner with a serious search burden

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 15, 17-19 and 22-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 4.

Status of Applicantion, Amendments, And/Or Claims

The amendment filed 11 April 2003 (Paper No. 4) has been entered in full. Claims 2-14, 16, 20, 21 and 26 are canceled. Claims 1, 15, 17-19 and 22-25 are withdrawn from further consideration as discussed above. Claims 27-59 are under examination.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33, 41, 49 and 57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. The specification as originally filed does not disclose nor suggest that administration of HMF can promote *removal* of malignant cells, as recited in the newly submitted claims. Also, the original claims do not recite that the administration of HMF to a patient promotes *removal* of malignant cells.

Claims 44-59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 44-59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The invention appears to employ novel biological materials, specifically ATCC deposit 75514. Since the biological materials are essential to the claimed invention they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the biological materials are not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the biological materials. The specification does not disclose a repeatable process to obtain the biological materials and it is not apparent if the biological materials are readily available to the public. It is noted that Applicant has deposited the biological materials (p. 4 of the specification), but there is no indication in the specification that the biological materials will be *irrevocably and without restriction or condition released to the public* upon the issuance of a patent. An affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological materials have been deposited under the Budapest Treaty and that, would satisfy the deposit requirement made herein.

Claims 27-32, 34-40, 42 and 43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

(1) a method for stimulating the proliferation and differentiation of hematopoietic progenitor cells comprising contacting bone marrow cells with an HMF protein comprising residues 2 to 142 of SEQ ID NO: 2 in an amount effective to stimulate the proliferation and differentiation of hematopoietic progenitor cells, either *in vitro* or *in vivo*, optionally wherein the HMF is administered to a patient suffering from leukemia;

(2) a method for stimulating the proliferation of bone marrow stromal cell colonies comprising contacting bone marrow cells with an HMF protein comprising residues 2 to 142 of SEQ ID NO: 2 in an amount effective to stimulate the proliferation of bone marrow stromal cell colonies, either *in vitro* or *in vivo*, optionally wherein the HMF is administered to a patient suffering from leukemia;

(3) a method for stimulating the proliferation and differentiation of T cells (including CD4+ and CD8+ T cells) comprising contacting T cells with an HMF protein comprising residues 2 to 142 of SEQ ID NO: 2 in an amount effective to stimulate the proliferation and differentiation of T cells, either *in vitro* or *in vivo*; and

(4) a method for stimulating the proliferation of thymocytes comprising contacting thymic cells with an HMF protein comprising residues 2 to 142 of SEQ ID NO: 2 in an amount effective to stimulate the proliferation of thymocytes, either *in vitro* or *in vivo*;

does not reasonably provide enablement for:

(1) treatment of patients having a general need of HMF;

(2) treatment of leukemia *per se*; and

(3) treatment of other blood-related disorders.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are directed to a method of treating a patient having need of HMF comprising administering HMF to the patient. The specification discloses the HMF protein of SEQ ID NO: 2, and discloses several biological activities of HMF. These activities include stimulating the proliferation and differentiation of hematopoietic progenitor cells, stimulating the proliferation of bone marrow stromal cell colonies, stimulating the proliferation and differentiation of T cells (including CD4+ and CD8+ T cells), and stimulating the proliferation of thymocytes. However, the specification does not disclose a correlation between any specific disease state and an altered level or form of HMF such that the skilled artisan is guided toward patients having need of HMF. For example, the specification indicates that it is known that leukemia is clinically featured by suppression of normal blood cell formation resulting from suppression of normal haemopoiesis by factors produced by leukemic cells (p. 11). However, there is no indication that HMF is capable of overcoming this suppression; i.e., that it is involved in a rate-limiting step that would affect the course of the leukemia itself. However, it is clear that HMF can stimulate the proliferation and differentiation of hematopoietic progenitor cells in a patient.

Due to the large quantity of experimentation necessary to determine which patients are in need of HMF, the lack of direction/guidance presented in the

specification regarding which specifi disease states can be successfully treated by administration of HMF, the absence of working examples directed to same, the complex nature of the invention, the unpredictability of the effects of any one factor on a complex disease state, and the breadth of the claims (some of which fail to recite specific disease states), undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

It is noted that claim 27 recites ATCC Deposit No. 75514. The biological deposit has not been perfects, as discussed in the rejection of claims 44-59 above. Thus, perfection of the deposit is also an enablement isse for claim 27.

Although claims 44-59 are not included in this rejection, it is noted that, if Applciant perfects the biological deposit, claims 44-59 would be included in the instant scope of enablement rejection for the issues discussed for claims 27-32, 34-40, 42 and 43 in the instant scope of enablement rejection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (703) 308-2673. The examiner can normally be reached on Monday through Thursday, 6:30 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne L. Eyler, Ph.D. can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

ECK

ELIZABETH KEMMERER
PRIMARY EXAMINER